

Arthur F. Simone, M.D., Ph.D.

Curriculum Vitae

(Updated: 11/15/18)

Office Address

Food and Drug Administration
Building 51; Room 5186
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Level of National Security Clearance

Secret (expires October 9, 2024)

Education

1978	B.S.	New Jersey Institute of Technology, Engineering Science
1981	M.S.	Pennsylvania State University, Bioengineering
1984	Ph.D.	Pennsylvania State University, Bioengineering
1988	M.D.	University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, Medicine
2008	Certificate	Georgetown University, Public Health

Postgraduate Training and Fellowship Appointments

1985-1986	Research Fellow, University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, New Brunswick, NJ
1988-1989	Transitional Internship, Presbyterian-Hospital of the University of Pennsylvania, Philadelphia, PA
1989-1992	Anesthesia Residency, Pennsylvania State University, Milton S. Hershey Medical Center, Hershey, PA

Professional Positions and Academic Appointments

1978-1984	Research Assistant, Bioengineering Program Pennsylvania State University,
1992-1996	Assistant Professor, Department of Anesthesia, Hospital of the University of Pennsylvania
1992-1996	Member, Graduate Group Committee, Department of Bioengineering, University of Pennsylvania

Professional Positions and Academic Appointments (continued)

- 1996 Staff Anesthesiologist,
Locum Tenens at Allegheny University Hospitals,
(Elkins Park Hospital and Warminster Hospital)
Arranged through Jackson and Coker Health Services, Inc.

- 1997-1999 Clinical Assistant Professor,
Department of Anesthesiology,
Allegheny University Hospitals, MCP-Hahnemann University

- 1999-2002 Clinical Assistant Professor of Anesthesiology,
Department of Anesthesiology, School of Medicine,
MCP-Hahnemann University

- 1999-2001 Chairman, Department of Anesthesiology, Elkins Park Hospital

- 2000-2001 Interim Chairman, Department of Anesthesiology, Warminster Hospital

- 2001-2002 Chairman, Department of Anesthesiology, North Penn Hospital

- 2002-2005 Medical Officer,
Division of Anesthetic, Critical Care and Addiction Drug Products,
Center for Drug Evaluation and Research (CDER),
Food and Drug Administration (FDA)

- 2005 Acting Lead Medical Officer, Anesthetic Products,
Division of Anesthesia, Analgesia and Rheumatology Products,
Center for Drug Evaluation and Research, Food and Drug Administration

- 2005-2015 Medical Officer,
Division of Anesthesia, Analgesia and Addiction Products,
Center for Drug Evaluation and Research, Food and Drug Administration

- 2015-2016 Acting Senior Medical Advisor,
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research, Food and Drug Administration

- 2016-present Senior Medical Advisor,
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research, Food and Drug Administration

Specialty Certification

- 1989-present Diplomate, National Board of Medical Examiners
- 1994-present Diplomate, American Board of Anesthesiologists

Licensure

1989-present Commonwealth of Pennsylvania State Board of Medicine

1996-present New Jersey State Board of Medicine

Awards, Honors, and Membership in Honorary Societies

1975	Tau Beta Pi (National Engineering Honor Society)
1978	Order of the Engineer
1978	Cum Laude with distinction in the Humanities, NJ Institute of Technology
2006	Commissioner's Special Citation (FDA)
2007	Excellence in Communication (CDER)
2009	Scientific Achievement Award – Outstanding Intercenter Scientific Collaboration (CDER/ORA)
2012	Regulatory Science Excellence Award – Cyanide Antidote Team (CDER)
2012	Office of the Chief Scientist – Biomarker/Repro-Tox Review Group
2013	Team Excellence Award – Sedation Workshop Team (CDER)
2015	Excellence in Communication Award – Epidural Steroid Injections Safety Review Team
2017	Office of Criminal Investigations Award – In appreciation and recognition of dedication and commitment to FDA's and OCI's joint mission of protecting the public health

Administrative Activities

1. Member, Ethics Advisory Committee,
Philadelphia Veterans Administration Medical Center, July, 1993 - June, 1996
2. Medical Director, Advanced Cardiac Life Support Training, Philadelphia Veterans Affairs Medical Center, April, 1994 - June, 1996
3. Member, C.P.R Committee,
Philadelphia Veterans Affairs Medical Center, September, 1994 - June, 1996
4. Member, Continuing Education Committee,
Pennsylvania Society of Anesthesiologists, July, 1998 - June, 2000
5. Member, Medical Executive Committee,
Elkins Park Hospital, April, 1999 - January, 2002
6. Member, Operating Room Committee,
Elkins Park Hospital, April, 1999 - January, 2002
7. Member, Invasive Procedures Review Committee,
Elkins Park Hospital, September, 1999 - March, 2002
8. Member, Medical Executive Committee,
Warminster Hospital, June, 2000 - June, 2001

9. Member, Operating Room Committee,
Warminster Hospital, June, 2000 -June, 2001
10. Member, Operating Room Committee,
North Penn Hospital, June, 2001 - January, 2002
11. Member, Food and Drug Administration Working Groups
 - a. Patient Controlled Analgesia (PCA) Safety
 - b. Auto Injector Guidance
 - c. Use of Color Coding for Differentiating Pharmaceuticals
 - d. Animal Rule Guidance Development
 - e. Combination Drug-Device Products
 - f. Infusion of Local Anesthetics
 - g. Data Standards Division Leads
12. Expert Reviewer
 - a. Program Advisory Group, SAFEKIDS (Safety of Key Inhaled and Intravenous Drugs in Pediatrics) Initiative, Office of the Commissioner, FDA, 2008 and 2009
13. Expert Witness
 - a. Nitrous Oxide (2010) - the safety of nitrous oxide inhaled from balloons or via gas masks connected to cylinders containing the gas product
 - b. Inhaled Nitrites (2010) – the risks associated with the use of nitrite products being sold as inhalants including: amyl, cyclohexyl, alkyl, and isobutyl nitrites.
14. Expert Panelist
 - a. Progress and Problems in Anesthetic-Induced Developmental Neurotoxicity: From Research to Regulation American Society of Anesthesiologists Annual Meeting, October 20, 2009
 - b. Closed Loop Drug Delivery Devices: Technology and Challenges CDRH and CDER Scientific Rounds, February 3, 2010
 - c. Pediatric Advisory Committee, June 21, 2010
 - d. American Society of Anesthesiologists and FDA Tele-Town on Drug Shortages, December 5, 2012

FDA Presentations

Expert Testimony

1. U.S. v. William Scully (No. 14-CR-208-ADS; New York, Eastern District)
October 15 and 19, 2015
2. U.S.A. v. Salim Lokhandwalla (No. 1:15-CR-252-MHC; Georgia, Northern District)
March 9, 2016
3. U.S.A. v. D. Anda Norbergs (No. 8:15-CR-183-JSM-AEP; Florida, Middle District)
November 8 and 9, 2016

4. U.S. v. Govinda Andiappen (No. 14-CR-402-ADS; New York, Eastern District)
December 12, 2016
5. U.S.A. v. Ismail Khan (No. 1:14-CR-197-SCJ; Georgia, Northern District)
February 10, 2017
6. U.S.A. v. Adams and Broombaugh (No. 14-CR-40005-DDC; Kansas)
February 23, 2017
7. U.S.A. v. George Patino (No. 4:16-CR-00055-HEA; Missouri, Eastern District)
June 6, 2017
8. U.S.A. v. Eric Potratz (No. 5:15-CR-00236-LHK; California, Northern District)
August 15, 2017
9. U.S.A. v. Gas Pipe, Inc., et al. (No. 3:14-CR-00298-M; Texas, Northern District)
October 3, 2018

External Presentations

1. Anesthetics and Life Support Drugs Advisory Committee Meeting: “Inapsine: Basis for Approval;” November 18, 2002
2. Anesthetics and Life Support Drugs Advisory Committee Meeting: “Propofol Product Development Issues;” November 19, 2003
3. Anesthetics and Life Support Drugs Advisory Committee Meeting: “Overview and Regulatory Issues Regarding Anesthetic Agents for Pediatric Patients;” March 29, 2007
4. Anesthetics and Life Support Drugs Advisory Committee Meeting: “Clinical Assessment of the Safety of Sugammadex;” March 11, 2008
5. Safe Use/Safety First Initiative: “Propofol: Safe Use;” July 29, 2009
6. American Society of Anesthesiologists Annual Meeting: “Wait or Regulate;” October 20, 2009
7. Pediatric Advisory Committee: “Brief Overview of Inhaled Anesthetics in the Pediatric Population;” June 21, 2010
8. Anesthetics and Life Support Drugs Advisory Committee Meeting: “Clinical Investigations of the Potential Effects of Anesthetics on Pediatric Neurological Development;” March 10, 2011

Internal Presentations

1. Anesthetics and Life Support Drugs Advisory Committee Meeting (closed session): “Diprivan Phase 4 Commitment: Sedation in the PICU – An Update;” November 10, 2005
2. Anesthetics and Life Support Drugs Advisory Committee Meeting (closed session): “A Tale of Two Antidotes – Treating Cyanide Toxicity;” November 10, 2005
3. Regulatory Briefing: “Clinical Implications of the Neurotoxicity Findings Associated with Anesthetic Agents;” January 6, 2006
4. CDER Scientific Rounds: “Application of the Animal Rule in the Development and Approval of Cyanokit®;” May 23, 2007
5. CDER Scientific Rounds: “Anesthetic Apoptosis and Babies’ Brains;” November 28, 2007
6. CDER Scientific Rounds: “Sugammadex: Hype and Hypersensitivity;” May 20, 2009
7. Center Director Briefing: “Update on Clinical Research on the Effects of Anesthetic Agents on Neurocognitive Development in Pediatric Patients;” August 24, 2010
8. Center Director Briefing: “Corticosteroids and Catastrophic Neurologic Events with Epidural Injection;” March 7, 2011
9. Office of Criminal Investigation All-Hands Meeting: “Expert Witness;” November 16, 2017

Bibliography

Articles

1. Simone AF: Longitudinal mixing in a cast of the human larynx. I.E.E.E. Transactions on Biomedical Engineering BME28 7: 493-495, 1981.
2. Simone AF and Ultman JS: Longitudinal mixing by the human larynx. Respirat Physiol 149: 187-201, 1982.
3. Simone AF and Ultman JS: Longitudinal mixing of oxygen with air during steady flow through the larynx. Bull Europ Physiopath Resp 18: 389-393, 1982.
4. Neubauer JA, Simone AF, and Edelman NH: Role of brain lactic acidosis in hypoxic depression of respiration. JAP 65(3): 1324-1331, 1988.
5. Simone AF, Ultman JS, and Jebria AB: Bronchial distribution of gas mixing in a model of the upper and central airways. JAP 65(4): 1693-1702, 1988.
6. Chang NS, Simone AF, and Schultheis LW: From the FDA: What’s in a label? A guide for the anesthesia practitioner. Anesthesiology 103(1): 179-185, 2005.

7. Schultheis LW, Mathis LL, Roca RA, Simone AF, Hertz SH, and Rappaport BA: Pediatric drug development in anesthesiology: an FDA perspective. *Anesth Analg* 103(1): 49-51, 2006.
8. Mellon RD, Simone AF, Rappaport BA: Use of Anesthetic Agents in Neonates and Young Children. *Anesthesia and Analgesia* 104(3): 509-520, 2007.
9. Rappaport B, Mellon RD, Simone A, Woodcock J: Defining Safe Use of Anesthesia in Children. *N Eng J Med* 364(15): 1387-90, April 14, 2011.

Abstracts

1. Ultman JS, Tarbell JM, Dreshsler DM, and Simone AF: Gas mixing in pulmonary airways during normal breathing. *Proc of the Assoc for the Adv of Med Instr* 16: 103, 1981.
2. Simone AF, Neubauer JA, Melton JE, and Edelman NH: Role for lactic acidosis in hypoxic depression of respiratory output. *Fed Proc* 45: 518, 1986.

Editorials

1. Ilivicky H, Caroff SN, and Simone AF: Etomidate during ECT for elderly seizure- resistant patients. *Am J Psychiatry* 152(6): 957-958, 1995.
2. Chang N, Simone A, Schultheis L, and Rappaport B: Reviewing Case Reports and the Droperidol Warning: FDA Response. *Anesthesia and Analgesia* 97(5): 1542, 2003.
3. Schultheis L, Mathis L, Roca R, Simone A, Hertz S, Rappaport B: Pediatric Drug Development in Anesthesiology: An FDA Perspective. *Anesthesia and Analgesia* 103(1): 49-51, 2006.

New Drug Applications (NDAs)

(Includes all NDAs for which clinical review and/or guidance were provided to the FDA and/or the Applicant)

<u>Number</u>	<u>Applicant</u>	<u>Product Name</u>
006488	Fresenius Kabi	Xylocaine w/ & w/o Epinephrine (Lidocaine w/ and w/o Epinephrine)
008816	Oak Pharmaceuticals	Xylocaine (Lidocaine) Jelly
008834	Abbott Laboratories	Tronothane Hydrochloride Cream & Jelly
008845	Hospira	Quelicin (Succinylcholine Chloride)
009435	Fresenius Kabi	Nesacaine (Chloroprocaine)
009470	Fresenius Kabi	Xylocaine (Lidocaine) Viscous
010417	Fresenius Kabi	Xylocaine (Lidocaine) 4% Preservative Free
010496	AstraZeneca	Xylocaine (Lidocaine) 5% W/ Glucose 7.5%
011338	Wyeth Ayerst Laboratories	Fluothane (Halothane)
011559	Par Sterile Products	Brevital Sodium (Methohexital)
012250	Hospira	Carbocaine (Mepivacaine)
014127	AstraZeneca	Xylocaine (Lidocaine)
014879	Eurohealth International	Dopram (Doxapram)
016297	Fresenius Kabi	Xylocaine 1.5% W/ Dextrose 7.5% (Lidocaine & Dextrose)
016619	Akorn	Sublimaze Preservative Free (Fentanyl)
016636	Adapt Pharma Operations	Narcan (Naloxone Hcl) Inj.
016812	Par Sterile Products	Ketalar (Ketamine)
016964	Hospira	Marcaine (bupivacaine)
017015	Organon	Pavulon (Pancuronium)
017087	Baxter Healthcare	Ethrane (Enflurane)
017398	Sandoz Canada	Regonol (Pyridostigmine)
017558	Eurohealth International	Robinul (Glycopyrrolate)
017624	Baxter Healthcare	Forane (Isoflurane)
018053	Hospira	Bupivacaine HCl
018227	Hospira	Amidate (Etomidate)
018692	Hospira	Marcaine (Bupivacaine)
018776	Organon	Norcuron (Vecuronium)
019353	Akorn	Alfenta (Alfentanyl)
019627	Fresenius Kabi	Diprivan (Propofol)
019638	Organon	Arduan (Pipcuronium)
019677	Mylan Institutional	Enlon Plus (Edrophonium & Atropine)
019946	Abbvie	Nuromax (Doxacurium)
019978	Hospira	Bupivacaine HCl
020073	Hoffmann-La Roche	Romazicon (Flumazenil)
020098	Abbvie	Mivacron (Mivacurium)
020118	Baxter Healthcare	Suprane (Desflurane)
020195	Cephalon	Fentanyl Oralet (Fentanyl)
020200	Abbvie	Nalbuphine HCl
020214	R-Tech Ueno	Zemuron (Rocuronium)
020478	Abbvie	Ultane (Sevoflurane)

<u>Number</u>	<u>Applicant</u>	<u>Product Name</u>
020551	Abbvie	Nimbex (Cisatracurium)
020575	Noven Pharmaceuticals	Lidocaine HCl
020630	Mylan Institutional	Ultiva (Remifentanyl)
020696	Paladin Labs	Antizol (Fomepizole)
020971	Deproco	Septocaine (Articaine with Epinephrine)
021038	Hospira	Precedex (Dexmedetomidine)
021380	Dentsply Pharmaceutical	Xylocaine (Lidocaine)
021381	Dentsply Pharmaceutical	Xylocaine Dental with Epinephrine (Lidocaine & Epinephrine)
021382	Dentsply Pharmaceutical	Citanest Plain (Prilocaine)
021383	Dentsply Pharmaceutical	Citanest Forte (Prilocaine & Epinephrine)
021451	Dentsply Pharmaceutical	Oraqix (Lidocaine & Prilocaine)
021504	Vyteris	LidoSite Topical System (Lidocaine & Epinephrine)
021623	Galen	Synera (Lidocaine & Tetracaine) Topical Patch
022010	Deproco	Septocaine (Articaine & Epinephrine)
022041	Serb SAS	Cyanokit (Hydroxocobalamin)
022046	Hospira	Bupivacaine HCl w/ and w/o epinephrine
022159	Septodont Holding SAS	OraVerse (Phentolamine)
022182	<i>redacted - not approved</i>	<i>redacted - not approved</i>
022225	Merck	Bridion (Sugammadex)
022466	Pierrel SPA	Orabloc (Articaine & Epinephrine)
201444	Hope Pharmaceuticals	Nithiodote (Sodium Nitrate; Sodium Thiosulfate)
204078	Eclat Pharmaceuticals	Bloxiverz (Neostigmine)
205579	Eagle Pharmaceuticals	Ryanodex (Dantrolene Suspension)